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| 10/674,186 | 09/29/2003 | Rudolph Nobis | END5212USNP | 2665 |

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| EXAMINER |
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KASZTEJNA, MATTHEW JOHN

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| ART UNIT | PAPER NUMBER |
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3739

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02/03/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|---|-------------------------------------|--|
| Office Action Summary | Application No. 10/674,186 | Applicant(s) NOBIS ET AL. | |
| | Examiner MATTHEW J. KASZTEJNA | Art Unit 3739 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-16 and 22-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-16 and 22-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 4, 2008 has been entered.

Notice of Amendment

In response to the amendment filed on December 4, 2008, amended claims 10-11, 14-16, 22 and 24 are acknowledged. The following new grounds of rejection are set forth:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-16 and 22-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "sized and shaped to be gripped/grasped by a single hand" in claims 10, 16 and 22 is a relative term which renders the claim indefinite. The term "sized and shaped" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be

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reasonably apprised of the scope of the invention. The size of users' hands may vary greatly and thus the terminology describing the size and shape of the handle is indefinite.

The term "a looped configuration behind the same hand" in claim 10 is a relative term which renders the claim indefinite. The term "behind the same hand" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The word "behind" is a relative term when a frame of reference is not provided (i.e. towards a proximal or distal end).

The remaining claims 11-15 and 21-26 are necessarily rejected as being dependent upon a rejected base claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-16 and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,443,944 to Doshi et al.

In regards to claim 10, Doshi et al. disclose a medical device comprising: a flexible member 15; an end effector 10a-b, 11a-b, 12a-b operatively associated with a distal end of the flexible member; and a handle 5 operatively associated with the proximal end of the flexible member (see Figs. 6-7); wherein the handle is sized and

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shaped to be gripped by a single hand; wherein the handle comprises an actuator 7a-b operable by the same hand for operating the end effector through the flexible member (see Col. 8, Lines 51-58) with a portion of the flexible member in a looped configuration behind the same hand, and wherein an outer surface of the handle is sized and shaped to be gripped by a single hand and wherein the actuator is disposed on the handle (see Col. 10, Lines 59-65). **In regard to claim 22**, the handle 5 comprises a release operatively associated with the end effector (see Col. 7, Lines 38-49). Doshi et al. disclose that the flexible member may be up to 50 inches long depending upon the particular application in which the device is to be used (See Col 4, Lines 10-32). Thus, if the flexible member 15, as seen in Figures 6-7, is constructed with a length of 50 inches, then the flexible member would be fully capable of being looped in any configuration around the hand as recited in the instant claims. Furthermore, it is clear from Figures 6-7, that a user would be fully capable of holding the handle with one hand, with the middle finger of that hand free to operate lever 7a-b and the index finger and thumb of the same hand free to manipulate the flexible member. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Furthermore, the words “to be” in the claim may be properly interpreted as “capable of,” and “capable of” does not require that reference actually teach the intended use of the element, but merely that the reference does not make it so it is incapable of performing the intended use.

In regards to claim 11, Doshi et al. disclose a medical device wherein the end effector is a grasping forceps (see Figs. 8a-c and Col. 6, Lines 11-20).

In regards to claims 12-13, Doshi et al. disclose a medical device wherein the flexible member has a length of at least 1 meter (see Col. 4, Lines 15-33).

In regards to claim 14, Doshi et al. disclose a medical device wherein the handle has a proximal end, a distal end, and an outer surface extending lengthwise intermediate the handle proximal and distal ends, with the handle outer surface having a maximum width portion disposed intermediate the handle proximal and distal ends, wherein the handle outer surface has a length that is greater than the width of the maximum width portion, and wherein the actuator comprises a lever 7a-b, the lever extending lengthwise alongside at least a portion of the handle outer surface, and wherein the lever extends alongside the maximum width portion of the handle outer surface (see Figs. 6-7).

In regards to claims 15 and 24, Doshi et al. disclose a medical device, wherein the actuator comprises a lever 7a-b positioned to be squeezed between fingers of the same hand holding the handle and a housing position of the handle, and wherein the lever extends alongside the housing portion of the handle, the lever having a length that is at least half the length of the handle (see Figs. 6-7).

In regards to claim 16, Doshi et al. disclose a system for operating a flexible endoscopic device with one hand comprising: an end effector 10a-b, 11a-b, 12a-b having a first and second configuration (See Figs. 8a-c), a handle 5, a flexible shaft 15

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extending intermediate the end effector and the handle; the handle comprising: a housing, the housing being longer than the housing is wide, and sized and shaped to be grasped by a single hand; an actuator 7a-b comprising a lever extending lengthwise alongside the housing (see Figs. 6-7) and operable by the hand holding the housing to actuate the end effector from a first configuration to a second configuration (See Col. 7, Lines 8-36) and a release 4 (see Col. 7, Lines 38-49).

In regards to claim 23, Doshi et al. disclose a medical device, wherein the release 4 is disposed at a first end of the handle and wherein the flexible member 15 extends from a second, opposite end of the handle 5 (See Figs. 6-7).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 25-26 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,443,944 to Doshi et al. in view of U.S. Patent No. 6,620,184 to de Laforcade et al.

In regards to claims 25-26, Doshi et al. disclose a system for operating a flexible endoscopic device with one hand (see rejections above) but are silent with respect to a release operable for returning the end effector to the first configuration. De Laforcade et al. teach of an analogous apparatus having a ratchet release mechanism

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for a medical device. The release mechanism permits both a smooth and a stepped actuation of a grasper on a distal end of the medial device. The medical device has a fixed handle and a movable handle. The release mechanism comprises an elongated toothed plate arrangement supported in a release housing and an elongated smooth plate arranged adjacent the toothed plate arrangement in the release housing. The release housing is pivotably supported between the handles to permit the handles to move in a stepped or a smooth manner to effect actuation of the grasper (see Figs. 1 and 2). It would have been obvious to one skilled in the art at the time the invention was made to include a release mechanism in the apparatus of Doshi et al. to provide a actuator that is simple to operate and inexpensive to manufacture and to provide a release mechanism which permits that medical grasper device to be multi-functional, to maintain and/or to immediately release a grasping or treatment configuration to that medical device as taught by de Laforcade et al.

Response to Arguments

Applicant's arguments with respect to claims 10-16 and 22-26 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW J. KASZTEJNA whose telephone number is (571)272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. J. K./
Examiner, Art Unit 3739

/Linda C Dvorak/
Supervisory Patent Examiner, Art
Unit 3739

1/28/09